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EXAMINER	
KIM, JOHN	

ART UNIT	PAPER NUMBER
3733	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,001	LEE, CASEY K.	
	Examiner	Art Unit	
	John Kim	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

Claims 25, 27, and 28 are objected to because of the following informalities:

Claim 25, refers to claim 23, where claim 23 is about a method and claim 25 is about an implant. In addition, both claims refer to an allograft that is capable of bearing 1000 pounds. The examiner takes note that claim 24 is about an implant. Thus, for examination purposes, claim 25 will be considered to refer to claim 24.

Claims 27 and 28 (method claims), refers to claim 25 and 26, respectively, where claim 25 is an implant claim and claim 28 would lack antecedent basis for "cross section. Thus, for examination purposes, claims 27 and 28 will be considered to refer to claim 26 and 27, respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 19, 20, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarborough et al. (US Pat 5,895,426).

Claim 1 refers to an implant that is composed of cancellous bone to be placed between vertebral bodies and an allograft. Scarborough teaches in his claims of having an intervertebral prosthesis comprised of an implant that is comprised of a cancellous bone (Col 8 ln 57 to Col 9 ln 20). For claims 2 and 20, he discusses that the bone may be autologous, allogenic or xenogenic. (Col 4 ln 35-6)

Claims 19 and 30 refers to a method of performing spinal fusion using a graft. Scarborough teaches about the prior art of interbody fusion (Col 1 ln 32 to Col 2 ln 46) and his procedure of spinal fusion (Col 6 ln 51 to Col 7 ln 40). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

For the reasons discussed above, claims 1, 2, 19, 20, and 30 in this application are anticipated by Scarborough.

Claims 1, 2, 8, 11-13, 15, 19-21, and 26-29 rejected under 35 U.S.C. 102(e) as being anticipated by Hanson et al. (US Pat App 10/080,375).

Claims 1, 2, 8,11, 12, discusses about a graft/implant made of cancellous bone to be implanted between vertebral bodies, where the graft is an allograft and the source is from the calcaneus. The applicant also discloses that the allograft is a solid body, shaped for insertion between two vertebral bodies, and is able to bear weight. The allograft can have a thin cortex surrounding the cancellous bone. Hanson teaches about an implant, made of bone, which may be an allograft and derived from the calcaneus. Hanson also discloses the preferred embodiment of the bone implant is cancellous (possibly surrounded by cortical bone) and provides examples of obtaining single pieces of allograft. (paragraph 62-3) In reference to claim 13, Hanson discusses that the "support component includes a material having mechanical properties suitable for providing, support, stabilization or alignment at the fusion site." (paragraph 65) This statement clearly shows that the implant must be able to be capable of bearing the weight of the human being. For claim 15, applicant describes an implant with a core of cancellous bone and surface of cortex bone. Hanson teaches several locations of obtaining a single piece with both cortical and cancellous bone. "These sources can provide an implant having cancellous bone surrounded on opposing sides by cortical bone." (paragraph 63)

Claims 19 –21 discuses about a method of performing a spinal fusion to implant a graft, where the graft is an allograft and made from calcaneus. As discussed above, Hanson had already discussed about the allograft made of calcaneus, and teaches about its implantation (starting from paragraph 91).

Claims 26-29 discusses a method of making an allograft from calcaneus Hanson, as discussed above, teaches that an allograft can be the calcaneus. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For the reasons mentioned above, claims 1, 2, 8, 11-13, 15, 19-21, and 26-29 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-7, 9, 10, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough et al. (US Pat 5,895,426).

In regards to claims 3-7, Scarborough teaches us that the implant is comprised of cancellous bone. It would have been obvious to one having ordinary skill in the art at

the time the invention was made to make an implant with various percentage of cancellous bone by volume since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claims 9 and 22, applicant discusses that the contact surface area be greater than 6 square centimeters. Scarborough teaches of having an implant of having a first diameter section range of 0.8-2 cm and a second diameter section of .2 centimeters less than the first. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make an implant with a surface contact area greater than 6 square centimeter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 24 and as discussed above, Scarborough teaches of having an implant that is made of allograft (Col 4 In 35-6), solid body of bone with at least 10% cancellous bone (Col 8 In 57 to Col 9 In 20), and being capable of bearing weight of a human being. For the last limitation, Scarborough teaches that "the graft should have enough structural integrity to withstand the stress of maintaining the space without substantially degrading or deforming and have sufficient stability to remain securely in place." (Col 2, In 11-15). With respect to the 10% limitation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make an implant with a certain amount of cancellous bone, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or

workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Cancellous bone allows for greater spinal fusion.

In regards to claims 10, 23, and 25, Scarborough teaches that the "support component includes a material having mechanical properties suitable for providing, support, stabilization or alignment at the fusion site." (paragraph 65) Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make an implant capable to bear the weight of 500 to 1000 pounds since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 3-7, 9, 10, 14, 16-18, 22-25, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson et al. (US Pat App 10/080,375).

With regard to claims 3-7, 9, 10, 14, 16-18, 22-25, 30, it would have been obvious to one having ordinary skill in the art at the time the invention was made to:

1) make an implant where the allograft is at least 60%, 80%, 95%, or 98% cancellous bone by volume.

2) make an implant where the surface area of the implant in contact with the vertebral bodies comprises of at least 98% cancellous bone.

3) make an implant/allograft where the contact surface area of the implant is greater than 6 square centimeters

4) make an implant where it is capable of bearing a load of greater than 500 pounds.

5) make an implant/allograft where it is capable of bearing a load of greater than 1000 pounds.

6) make an implant where the surface area in contact between the intervertebral bodies and the implant comprises at least about 90% or 98% cancellous bone

7) make an implant where it has a thickness between 0.5cm and 5cm.

8) make an allograft with a solid body and having at least 10% cancellous bone by volume and shaped for placement, where the implant is capable to bear the weight of a human

9) perform a spinal fusion where a) a graft is substantially made of cancellous bone, b) stored, c) and implanted in the spine

Though Hanson does not disclose expressly the limitation stated above, he discloses the materials (bone derived, paragraph 62) to make the implants. Furthermore, Hanson teaches that the implant needs to have the mechanical properties suitable for providing, support, stabilization, or alignment at the fusion site and have the mechanical or physical properties that allow or support new bone in-growth. (paragraph 63) It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It has also been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Thus it would be

obvious to one skilled in the art to modify Hanson to obtain the invention as specified in the above-mentioned claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK

EDUARDO C. ROBERT
PRIMARY EXAMINER